Draft Policy on Antimicrobial Use and Resistance

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Current trends in resistance in Ghana

The discovery of antimicrobials has played an important role in decreasing morbidity and mortality due to infectious diseases. The success of infectious disease treatment has been one of modern medicines greatest achievements. Expansion and improvement in health systems and resources, coupled with production technologies across the world has also led to increase in availability and access to antimicrobials. Over the years, improved access to antimicrobials has been accompanied by poor practices that have contributed to microbes developing resistance to these life-saving medicines.

The emergence and spread of antimicrobial resistance has been recognized as one of the major regional as well as global health problems today. (WHO, 2013)

Antimicrobial resistance (AMR) is resistance of a microorganism to an antimicrobial drug that was originally effective for treatment of infections caused by it. (WHO, 2013)

Antimicrobial resistance results in prolonged illness, increased burden on health systems and insurance schemes. It also hampers the control of infectious diseases, increases the cost of healthcare, affects health security, damages trade and economies and threatens a return to the pre-antibiotic era. (WHO, 2013). Prolonged ill-health may result in loss of man-hours and productivity and hence loss of income to the family and the nation at large.

Antimicrobial resistance is a global problem, and it is compounded in low-resource countries.

The threat of antimicrobial resistance (AMR) cannot be overemphasized as it affects commonly used and affordable antimicrobials. The need to address this precarious situation now is key to preserving the effectiveness of antibiotics and saving future generations.

There are several factors that contribute to development of resistance. These include:

- Irresponsible or inappropriate use of Antimicrobials
- Lack of information on the proper use of Antimicrobials
- Absence of policy on Antimicrobial use
- Spurious, Substandard, Falsified, Fake and Counterfeit Antimicrobials
- Unregulated access to Antimicrobials
- Use in agriculture as growth promoters
- Poor infection prevention and control in health facilities
- Poor environmental sanitation
- Poor or absence of surveillance on Antimicrobials use
- Poor knowledge on Antimicrobials resistance

Antimicrobial resistance (AMR) is resistance of a microorganism to an antimicrobial drug that was originally effective for treatment of infections caused by it. (WHO, 2013) Resistant microorganisms (including bacteria, fungi, viruses and other parasites) are able to withstand attack by antimicrobial drugs, such as antibacterial drugs, antifungals, antivirals, and antimalarials, so that standard treatments become ineffective and infections persist, increasing the risk of spread to others.

The evolution of resistant strains is a natural phenomenon that occurs when microorganisms replicate themselves erroneously or when resistant traits are

exchanged between them. The use and misuse of antimicrobial drugs accelerates the emergence of drug-resistant strains.
The overall primary drug resistance rate of 23.5% in Ghanaian TB patients ranks Ghana among those African countries with a high prevalence of drug-resistant TB. (Owusu-Dabo & Ohene, 2006)

Global trends in antibiotic resistance

WHO reports that, about 440 000 new cases of multidrug-resistant tuberculosis (MDR-TB) emerge annually, causing at least 150 000 deaths (WHO, 2013). Extensively drug-resistant tuberculosis (XDR-TB) has been reported in 64 countries to date. It is also reported that, a high percentage of hospital-acquired infections are caused by highly resistant bacteria such as methicillin-resistant *Staphylococcus aureus* (MRSA). AMR has become a serious problem for treatment of gonorrhoea (caused by *Neisseria gonorrhoeae*), involving even "last-line" oral cephalosporins. This phenomenon is increasing in prevalence worldwide. Untreatable gonococcal infections would result in increased rates of illness and death, thus reversing the gains made in the control of this sexually transmitted infection. Inappropriate and irrational use of antimicrobial medicines provides favourable conditions for resistant microorganisms to emerge, spread and persist. (WHO, 2013)
Resistance is also an emerging concern for treatment of HIV infection, after the rapid expansion in access to antiretroviral drugs in recent years; national surveys are underway to detect and monitor resistance.
At the end of 2011, more than 8 million people were receiving antiretroviral therapy in low- and middle-income countries to treat HIV. Although it can be minimized through good programme practices, some amount of resistance to the medications used to treat HIV is expected to emerge.
Analysis of data from WHO surveys that target people who have been recently infected with HIV indicates increasing levels of resistance to the non-nucleoside reverse transcriptase (NNRTI) class of drug used to treat HIV. This increase is particularly noticeable in Africa, where the prevalence of resistance to NNRTI reached 3.4% (95% CI, 1.8-5.2%) in 2009.
Over the past 10 years, antiviral drugs have become important tools for treatment of epidemic and pandemic influenza. It was estimated that, by 2012, virtually all influenza A viruses circulating in humans would be resistant to drugs frequently used for the prevention of influenza (amantadine and rimantadine). Antiviral susceptibility is constantly monitored through the WHO Global Surveillance and Response System.

Trends in African countries

In Africa, antibiotics are among the commonest prescribed medicines. A survey on predictors of antibiotic use in five countries in Africa showed that 90% of individuals with acute illness sought care outside the home with 95% receiving medicines and 36% received antibiotics. Of the antibiotics received, cotrimoxazole, amoxicillin and metronidazole represented 75% of received antibiotics. Over 30% of individuals accessed antibiotics without prescription and one in four individuals obtained antibiotics from an informal dispenser.

This survey also reported various levels of resistance to antibiotics in the sampled countries. (Newman, Frimpong, Donkor, & Opintan, 2011), (WHO, 2013)
Many African countries reported the presence of resistant strains of bacteria. For instance, in Nigeria, there is high resistance to Vancomycin, Gentamycin, Chloramphenicol and Cloxacillin. (Omolu, 2002)

Trends in Ghana

Various studies carried out proved the existence of antibiotic resistance in Ghana. A study in 2 teaching, 7 regional and 2 district hospitals in Ghana showed that, very common microbes such as streptococci, salmonella, and *E. coli* showed very high levels of multiple drug resistance some as high as 78.7%. In the various hospitals sampled, the prevalence of resistance to common and affordable antimicrobials like tetracycline, co-trimoxazole, ampicillin and nalidixic acid are significantly high (largely above 70%) (Newman, Frimpong, Donkor, & Opintan, 2011), (Nweneka, 2009)
In another study carried out in 2007 in some key health facilities among inpatients and out patients, specimens taken from various sources including wounds, urine, sputum and blood, showed high prevalence of MRSA. (Newman, Frimpong, Donkor, & Opintan, 2011)
Resistance to common antibiotics has been identified in other studies, based on isolates of *Staphylococcus aureus* from Inpatients and hospital staff at Korle Bu Teaching Hospital. See table below:

Antibiotic resistance of *Staphylococcus aureus* isolates from inpatients (IP) and hospital staff (HS) at Korle Bu Teaching Hospital, Ghana, 2011–2012.

Antibiotic	*n* (%)		
	IP (*N*=63)	HS (*N*=42)	Total (*N*=105)
Penicillin	62 (98)	36 (86)	98 (93)
Tetracycline	21 (33)	8 (19)	29 (28)
Fusidic acid	11 (17)	2 (5)	13 (12)
Cefoxitin	6 (10)	0 (0)	6 (6)
SXT	3 (5)	0 (0)	3 (3)
Erythromycin	4 (6)	1 (2)	5 (5)
Clindamycin	3 (5)	0 (0)	3 (3)
Norfloxacin	2 (3)	0 (0)	2 (2)
Gentamicin	1 (2)	1 (2)	2 (2)
Rifampicin	1 (2)	0 (0)	1 (1)
Mupirocin	0 (0)	1 (2)	1 (1)
Linezolid	0 (0)	0 (0)	0 (0)

SXT, trimethoprim/sulfamethoxazole.

Further more, other evidence in Ghana suggests that, many infectious pathogens are failing to respond to common, potent and easily accessible antibiotics in the health system and thus resulting in increased morbidity and mortality from infections. (Nweneka, 2009)
The absence of national antibiotic use policy that guides the use and control of resistance is also contributing immensely to the upsurge in abuse of antibiotics at the community and the institutional level across the country. (Gyansa-Lutterodt M, 2013)

Use of Antimicrobials in veterinary and aquaculture

The use of antibiotics for disease prevention and growth promotion in animal husbandry, and the existence of antibiotic residues in the food chain are also likely to compound the problem of antibiotic resistance. (Schmidt, 2009), (Le, 2005). (Donkor, Tetteh-Quarcoo, Nartey, & Agyeman, 2012)

Antibiotics are used in livestock for purposes including treatment and prophylaxis against infections. It is also used in sub-therapeutic doses in livestock feeds to enhance growth and improve efficiency of feeds in intensive livestock farming.

The non-therapeutic use of antimicrobials in livestock production has increased tremendously. The Onion of Concerned Scientists report that about 90% of antimicrobials used in the USA was for non-therapeutic use (Onion of Concerned Scientists, 2001). The commonly used antibiotics in humans that are being used in animals for non-therapeutic purposes include tetracycline, penicillin and erythromycin.

The *Veterinary Public Health and Food Safety Unit* is presently the main unit responsible for monitoring the use of antibiotics and surveillance of resistance in animals. The overall goal of the *Veterinary Public Health and Food Safety Unit* is to prevent zoonotic diseases in humans and assure food safety. There are also plans to carry out antibiotic residue testing and Antibiotic resistance testing in the veterinary public health laboratory. Meanwhile the veterinary services are poorly resourced with outlets poorly distributed in country. Public knowledge on veterinary services is also minimal. Collaboration is mainly in the area of zoonotic diseases and not on antimicrobial resistance. (Kikimoto, 2014)

The FDA is responsible for the registration; post market surveillance and quality assuranceof all medicines including those used in veterinary services. The FDA also regulates the importation of antibiotics for veterinary use. (Ghana Public Health Act, 851, 2012)

Antibiotic resistance has not been a priority for the veterinary services in Ghana.There are no acceptable national standards for; antibiotic residue in veterinary and aquaculture produce; no testing for antibiotic residueis done; the minimum allowable weaning period before slaughter and processing.

A case study from Ghana on the presence of beta Lactamase producing *Escherichia coli* and *klebsiella pneumoniae* isolates as well as tetracycline residues in chicken meat established the occurrence of drug resistance among E.coli and K. pneumoniae strains isolated from chicken meats bought in Ghana. In addition high incidence of tetracycline residues were found in the chicken meat samples. (Rasmussen, 2014)

Another study on the presence of antimicrobials and resistance in healthy subjects from greater Accra concluded that 74.2% of study subjects showed the presence of at least one antibiotic in their urine, although all (100%) of the study participants had not knowingly consumed antibiotics. This call for further investigation as maybe possible that people are consuming antibiotics from alternate sources such as food and water (Hane-Weijman & Trads, 2014)

There is anecdotal information on the use of antibiotics in aquaculture especially in fish farming. There is no department/unit responsible for antibiotic use and surveillance in aquaculture as well as the monitoring of residual antibiotics in fish.
Some antibiotics used in both humans and animals locally include:

- Tetracyclines
- Chloramphenicol
- Streptomycin
- Penicillin

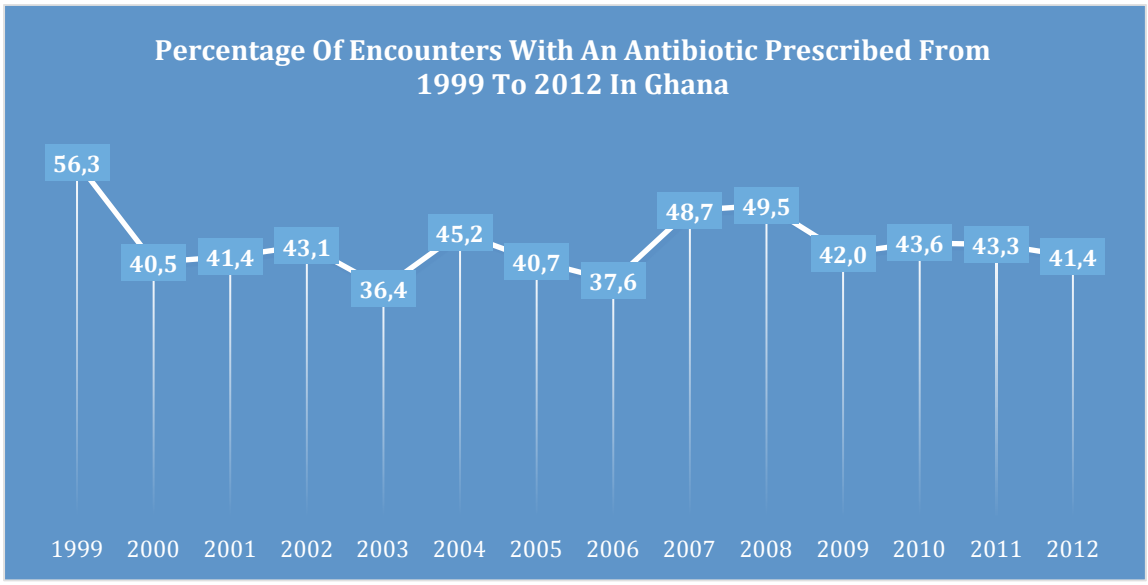
Key issues

The key issues include:

1. Widespread indiscriminate use of antibiotics by veterinary officers, farmers, general public (including use in household rearing of animals) and quack veterinary doctors in animal health delivery.
2. Absence of monitoring mechanisms for the use of antibiotics in veterinary and aquaculture
3. Absence of veterinary standard treatment protocols for use veterinary and aquaculture
4. Lack of appropriate legislation.
5. High illiteracy rate and lack of public education programmes
6. The veterinary department is poorly resourced
7. General lack of public recognition for veterinary services and functions
8. Inadequate veterinary drug and service outlets across the country
9. Human drugs are procured for use in veterinary and aquaculture
10. Weak collaboration amongst stakeholders
11. Antibiotic residue in animals is not being measured. There is no acceptable national standards for; antibiotic residue in veterinary and aquaculture produce, no such testing is done
12. The minimum allowable 'wash-out' period before slaughter and processing is not adhered to

Rational use of Medicines

Since 1998, Ghana has been implementing the rational use of medicines programme, with the aim of improving medicine use. The rational use of medicines concept demands that patients receive medicines appropriate to their clinical needs in doses that meet individual requirements and for the right duration.
The Ghana National Drug Policy recommends routine monitoring of rational use of medicines. The WHO core indicators were adopted for use in the country, which includes only one indicator on antibiotic use i.e. 'the percentage of encounters with antibiotic prescribed'. Since the implementation of the programme, antibiotic use at the OPD level has reduced from 56.3% in 1999 to 41.4% in 2012. (Ghana Health Service (OCP), 1999-2012)



In the implementation of the RUM programme, Drugs and Therapeutic Committees (DTCs) were formed in majority of the teaching, regional, district, some quasi hospitals, and trained in medicines management. Part of their functions includes the monitoring of antibiotic use in the facility. However, this function is not being performed in a majority of health facilities. Some facilities have developed guidelines to improve prophylactic antibiotic use in surgery; and also in the use of third generation cephalosporin. The use of antibiotics in inpatients has not been given adequate attention.

Self-medication is a common practice in Ghana. Prevalence of self-medication in a study by (Donkor, Tetteh-Quarcoo, Nartey, & Agyeman, 2012) showed a high prevalence of 75% amongst tertiary students. The most common antibiotic used was amoxicillin.

At the community level, antibiotics are widely and freely available in the market places, the roadside, lorry stations, buses, as well as 'freelance medicines vendors' in the villages, and chemical sellers. (Health Summit, 2014). The sources of these antibiotics are unknown and quality cannot be guaranteed. The dosage, route of administration, duration of administration do not follow standard protocols.

At the health facility level, there are inappropriate prescriptions of antibiotics. The levels of prescribing are not adhered to; dangerous drug books are not kept and managed. Due to poor laboratory setup, culture and sensitivity testing is not done. Where they exist, the sensitivity patterns are not reviewed at the facility levels. There are instances especially at the OPDs where laboratory results show resistance to a particular antibiotic but patients are still treated on these antibiotics. Health professionals sometimes also prescribe antibiotics when not needed.

Traditional medicine practice is another area where antibiotics are abused. There are reported cases by the FDA where antibiotics have been used to adulterate some herbal products. In some instances at the community level, patients suffering from gonorrhea are advised by traditional medicine practitioners to add antibiotics to their herbal products for treatment.

Key issues

Key issues include:

1. Only one indicator is being monitored routinely on antibiotic use
2. Widespread and inappropriate use of antibiotics
3. Levels of prescribing and STGs are not adhered to
4. SSFFCs antibiotics in circulation
5. Non adherence to treatment by patients
6. Self medication
7. Easy access to antibiotics in the open market, on the roads, in buses, in licensed and unlicensed premises/sources and lack of access as a result of poor health systems
8. Use of antibiotics in traditional medicines
9. Unregistered persons prescribe antibiotics
10. Dangerous drug book not kept and managed at health facilities
11. Data on level of combination of antibiotics and the type of antibiotics prescribed at the OPD level is not readily available
12. Prescribing antibiotics when they are not indicated
13. Prescribing of antibiotics is not informed by culture and sensitivity testing
14. Inadequate counselling of patients on use of antibiotics in hospitals leading to non-compliance
15. Financial barriers resulting in non-compliance to treatment
16. Inappropriate storage of antibiotics
17. The frequent change from one antibiotic to another in the course of treatment due to uniformed prescribing

Infection prevention and control:

Public/Home/Community

(Donkor, Tetteh-Quarcoo, Nartey, & Agyeman, 2012) reported significant levels of self-medication amongst tertiary students. This practice is known to the general and widespread and extends to the communities.
Antimicrobial policies therefore should be responsive to the medicines needs of the general public and communities as well.

Hospitals

In 2005 an assessment of Infection Prevention and Control (IPC) was carried out involving 33 health facilities comprising 12 hospitals and 21 health centres in the 3 geographical zones (northern middle and southern), of the country. Although some examples of good practices were observed in a few of the facilities, practices generally fell below acceptable levels. There was no significant difference in practices in the different levels of service delivery. (Ghana Health Service (ICD), 2005)
Findings include:

- Inappropriate methods for processing used instruments
- Improper hand washing practices

- Inability of most staff to maintain aseptic techniques in clinical procedures
- Improper use or non-availability of protective clothing
- Problems with environmental cleaning and healthcare waste management

These contribute to the spread of healthcare associated infections, which are often difficult to treat.
In 2011, a national policy on infection prevention and control was developed and some health workers were trained. Dissemination to health workers has been limited to only a fraction of staff due to inadequate resources.
The use of alcohol hand rub has also been introduced. However IPC practices are still inadequate. (Ghana Health Service (ICD), 2011)
Health Care Associated Infections (HAI) are a major threat to patient safety worldwide including Ghana. Transmission is mainly from the hands of healthcare workers. Healthcare facilities are also important sites for the development of antimicrobial resistance, because of the intensity of antimicrobial use together with populations highly susceptible to infections, which create an environment that facilitates the emergence, and transmission of resistant organisms.
Good infection prevention and control programmes in health facilities reduce the frequency of healthcare associated infections.
There has been slow progress in improving hand hygiene practices across patient care points within healthcare facilities. An Emergency, Obstetrics and Neonatal care study in 2011 showed 8% of facilities out of 1268 had no water source. In one region, 25% of health facilities out of a total of 96 had no water source. These have great implications for hand hygiene practices.
In the absence of hand washing sinks and running water, ''Veronica buckets'' are commonly used in most health facilities. However recent studies have shown contamination of water in these containers with microbes due to inadequate cleaning.
There are very few hand washing and toilet facilities for patients in the healthcare setting. Although the use of alcohol hand rubs is gaining grounds they are not readily available in all patient care areas. There are also gaps in their application.
In a study done by (Asare et al),, compliance to Hand Hygiene recommendations before versus after patient contact was 15.4% and 38.5% for physicians, 4.1% and 9.9% for nurses. Gloves were used for 60.8% of patient contacts (85.7% high-risk, 35.4% low-risk); however compliance to recommended procedure occurred in only 12.2% of high risk contacts and none of the low risk contacts. Gloves were not changed between patients in 43.7% of high-risk contacts and 88.2% of low-risk contacts. Although alcohol hand rubs was always available, it was not used for hand hygiene.
Another study in a hospital on the prevalence of wound infection by (Apanga et al), showed that the prevalence of wound infection was relatively high with nosocomial wound infection accounting for approximately 40% of the total would infections.

In 2012, there was an outbreak of Methicillin Resistant *Staphylococcus aureus* (MRSA) in the child health department of the Korle Bu Teaching Hospital. All the wards in the department were swabbed and positive results were found in several wards. MRSA was found in various areas including infected babies, staff and the environment. (Newman M. , 2014)

Waste Management

The provision of health care like any other human activity generates wastes, which have to be managed or disposed of in a safe manner in order to minimize risk to the health of health-workers, clients and community at large. However, 10-25% of waste generated in health facilities are harzardous, and require special arrangement for management. Examples of hazardous health care wastes are pathological waste such as tissues and body fluids, pharmaceuticals (expired and unused drugs), sharps (syringes, disposables, scarpels etc).

Poorly handled healthcare waste can result in healthcare associated infections, which are often difficult to treat because of antimicrobial resistance.

There is an MoH waste management policy developed in 2006 that seeks to ensure that, health care waste is managed effectively in compliance with existing laws and regulations and others to be passed in future in order to protect health care workers, their clients (patients, caregivers and visitors) and the environment from potentially disease-causing waste materials. The Guidelines provide standards, procedures and processes for handling health care waste in the sector institutions and mechanisms for performance and performance monitoring.

There is slow progress in improving healthcare waste management. Waste is often not segregated, where sharps are collected in separate containers, the containers are often left to overflow.

Color coding practices are not often adhered to. Open dumping is a common practice, however, where incinerators are provided their maintenance and use is hampered by lack of resources.

Key issues:

- Poor hand hygiene practices amongst health workers and the community
- Inadequate logistics and supplies for IPC
- Inadequate implementation of the IPC and Waste management policies
- Poor environmental cleaning and healthcare waste management

Laboratory diagnostics and protocol requirements:

Preamble

There are structures in place to support the provision of laboratory services for health care. The goal of the structures in place is to ensure optimal delivery of laboratory services for the various levels of healthcare delivery for both public and private sectors. This service is to ensure that the antimicrobials introduced are specific for the disease causing microbe and contribute to the containment of antimicrobial resistance.
There are various medical lab providers as shown below:

Providers of medical lab services:

University Medical Research labs	NMIMR labs KCCR labs
Ministry of Health	**Teaching Hospitals** Teaching hospital labs **GHS** Health research division (Kintampo HRC, Navrongo HRC, Hohoe HRC, Dodowa HRC) ICD, hospital labs (Clinical lab units: Regional Hospital labs, District Hospital labs, Health centre / sub district hospital labs) Public Health Division (National Public Health Reference labs: zonal public health labs 4 (3+1 greater accra) – Western region-EffiaNkwanta, Accra-Korle-Bu TH, Tamale TTH, Kumasi South Hospital. **National blood transfusion services labs**
Ministry of defense	Armed forces hospital labs
Private hospital independent labs	Private hospital labs Standalone labs
Ministry of Interior	Ghana Police labs Prisons labs

The other stakeholders for the medical labs sector include:

- FDA
- GSA
- PSGH
- Ghana Association of Biomedical laboratory scientist GABS
- Association of private medical labs Ghana, APMLGh

- Christian Health Association of Ghana, CHAG
- Teaching hospitals

A large majority of primary care labs do not have the capacity to do microbiology tests due to inadequate capacity, inadequate human resource, equipment and reagents.
Culture and sensitivity not done in most cases-

- In most cases, clinicians do not request for sensitivity test for diagnosis and treatment
- Weak capacity of some labs to do sensitivity testing
- Sensitivity testing done are based on what drug agents provide

A national lab policy has recently been developed, which recommends testing for culture and sensitivity at the primary level (district hospitals).

Key issues

Key issues include:

- Unauthorized laboratory staff prescribing antibiotics
- Culture and sensitivity not done in most case; leading to patients being blindly treated. This may result in prolonged illness where there is no response to therapy and leads to high-mortality
- G-DRG payment mechanisms make it difficult to know the cost of lab services provided
- Human resource issues – inadequate numbers, poor distribution and no motivation for laboratory personnel to upgrade
- No national platform for collation of data on culture and sensitivity testing
- No standardised laboratory reporting format
- Turnaround time/delay in the release of lab findings is a de-motivation factor to request for culture and sensitivity testing prior to therapy
- No standardized culture and sensitivity plate

National surveillance system for antibiotics

Preamble

Surveillance of antimicrobial resistance is done to track changes in microbial populations, detect early resistant strains of public health importance and support the prompt notification and investigation of outbreaks.
Surveillance findings are required to inform clinical therapy decisions, to guide policy recommendations and to assess the impact of resistance containment interventions.
National surveillance system for antibiotics exists for very few programme drugs e.g. TB and HIV. There is a general disease surveillance mechanism in Ghana as well as for specific programmes. An assessment of the TB surveillance system in Ghana reveals some favourable findings. The

surveillance system is paper-based, based on the WHO-recommended structure of quarterly reporting of aggregated data. It covers health facilities in 170 districts in 10 regions. An electronic recording and reporting case-based surveillance system is not in place. The 2013 assessment also reveals that there is ongoing deployment of software for transition to such an electronic system.
Some of the markers of data quality in the surveillance system includes:

- Standardization and consistency with international standard (ie. WHO)
- Surveillance system designed to capture a minimum set of variables for relevant cases
- Scheduled and adequate periodic data submissions (reporting) received and processed at the national level
- Accuracy, completeness, internal and external consistency in data
- Surveillance data provide a direct measure of drug resistant TB in new cases

(Bonsu & Boateng, 2013)

Key issue:

- This is largely non-existent for all other antibiotics.

Regulation and enforcement

The FDA and Pharmacy council are responsible for medicine regulation and enforcement. FDA regulates the manufacture of local antibiotics as well as the importation; however there are concerns about high levels of substandard spurious fake falsified counterfeits (SSFSCs) antimicrobials on the market. Study by Bekoe S., showed that antibiotics supplies from the informal sector were of lower quality than those from the formal sector (Bekoe, 2014). The importation through unapproved routes makes regulation difficult. The sale of antimicrobials on the open markets, vehicles and unapproved locations is also a source of concern.
Legal framework:
The mandate for FDA for regulation comes from the Public Health Act and has developed guidelines and SOPs for their operations. Their activities include monitoring of safety profiles of antibiotics used in Ghana, providing technical support to local manufacturing industries, conducting post market surveillance of products and are responsible for evaluation and registration of antibiotics in general. The Health professionals practice is regulated by the Health Professionals Regulatory Act.
The overall legal framework for medicines including antibiotics is set out in the Public Health Act and enforced by the FDA. Professional bodies regulating the practice of health in general are provided for in the Health professionals body regulatory Act. There are no specific provisions on antibiotics in these Acts.
Policy, Administrative and management framework:
The policy framework for the regulation of antibiotics is weak or non-existent. The existing policies of essential medicines in general do apply to antimicrobials. There is however, a specific policy intervention for infectious

diseases such as malaria, TB and HIV, which has been under global fund support over the years.

Key issues

1. Although antibiotics are prescription only medicine they're dispensed over the counter by most practioners including licensed chemical sellers.
2. There is also the issue of misuse of patients as full courses prescribed are not adhered to, the immediate impact leads to therapeutic failure.
3. Weak post market surveillance system.
4. Affordability for patients where patients can't afford the full cost of antibiotics prescribed.
5. Inadequate human resource.
6. Target of profits making by pharmacist over professional ethics and pharmaceutical care
7. Smuggling of counterfeits antibiotics into the country.
8. Weak pharmacovigilance system.
9. There is need for training and general public education about the use of antibiotics
10. FDA to intensify post market surveillance to ensure compliance with distribution of antibiotics regulation.

Antibiotic Manufacturing, Distribution and Use

The Private sector is the main actor when it comes to manufacturing of medicines including antibiotics. Government's roles only come in providing incentives (tax incentives) for the private sector.

There are currently about 38 pharmaceutical manufacturing companies in Ghana, though not all are active. The local industry has the technology for both active pharmaceutical ingredients, packaging and finished dosage forms manufacturing. The industry produces medicines for a wide variety of therapeutic uses, including antibiotics. About 30% of the essential medicine needs of Ghana are met through local manufacturing with the rest mainly by import from other countries. This huge import unfortunately leaves room for illegal activities such as importation of fake, counterfeit and sub-standard medicines including antibiotics.

There are plans to establish a bioequivalent centre that will help assure quality of antibiotics produced or procured into the country.

No local company is in the production of antibiotics from the API to the finished product.

Most of the pharmaceutical companies do not produce antibiotics but are involved in contract manufacturing and importation from companies; mainly India and China. These companies receive finished products, which are packaged and shipped to the country.

Distribution of pharmaceuticals including antibiotics

Distribution of medicines is characterized by complex interaction between the public, self-financed and faith-based sectors.

Antibiotics distribution does not follow a specified system. The distribution is as occurs with other essential medicines. Ghana operates a pull system for

essential drugs where facilities decide periodically what they require and purchase either from the next level or from the private sector.
Medicines including antibiotics are procured through the public procurement arrangements, which are regulated by various Acts and Legislations. These essential medicines are received by the publicly owned Central Medical Stores (CMS) for warehousing and distribution to the various Regional Medical Stores and health facilities in the public and private sectors.
Due to the decentralized procurement arrangement system in the health sector, health facilities are also allowed to procure outside the Central Medical Stores within an agreed and regulated threshold value. Some private groups such as Christian Health Association of Ghana (CHAG), procures and distributes medicines including antibiotics to its members.
Most of the major manufacturers have an integrated distribution business with fixed distribution points in several regions and mobile vans that make scheduled tours to deliver medicines to more remote locations.
Medicines including antibiotics are also imported and distributed by licensed private wholesalers across the country. (Seiter & Gyansa-Lutterodt, 2009) indicate that about 150 companies are licensed or registered national or regional wholesalers of pharmaceutical products. The total number of businesses involved in active drug import and distribution including antibiotics is between 200 and 300.
Due to the free market and poor enforcement of regulations, antibiotic distribution cannot be tracked easily. Unrestricted access makes it possible for untrained persons to access and distribute antibiotics. Limited number of health cadres and their poor distribution to the rural areas has created a delicate balance between access and proper antibiotic therapy.
The porous borders also allow antibiotics whose quality cannot be ascertained into the health system.
(Seiter & Gyansa-Lutterodt, 2009), (Ministry of Health, 2010)
Antibiotics are freely accessible and used by all though legislation exist to regulate access. Pharmaceutical wholesalers supply antibiotics to both the public and private sectors. Government facilities being the main public sector while the private sector includes: registered pharmacies, chemical sellers and direct consumers. There is no written strategy to monitor the use of antibiotics with the exception of INRUD indicator on the proportion of antibiotics prescribed. Percentage of encounters with antibiotics prescribed is about 43% (Medicines Transparency Alliance Ghana, 2010). Prescribing by national guidelines is not being adhered to. Non-pneumonia acute ARI of any age treated with antibiotics stood at 100%. Antibiotics are freely accessible without prescription.
The following are the stakeholders with role to play in the manufacture and distribution of antibiotics
MOH/GNDP: Define drug policy and coordinate implementation of the policies and programs of the pharmaceutical sector; monitor certain performance parameters such as, rational use; issue Standard Treatment Guidelines and Essential Medicines List
FDA: Regulates pharmaceutical market, manufacturing, import, export, advertising, clinical trials

NHIA: influences prices through regulation (maximum reimbursement) and prescription practices through claims management
Pharmacy council|: Regulatory body that licenses retail pharmacies and chemical sellers
Procurement and supply procure drugs for the public sector supply system
CMS: Warehousing and Distribution
PMAG: Pharmaceutical Manufacturers Association of Ghana; main interest is to improve business perspectives of local manufacturers (Seiter & Gyansa-Lutterodt, 2009)
- National Public Health Programmes
- Christian Health Association of Ghana – procurement, distribution and use
- Health Professional associations (GMA,GRNA,PSGH,etc..)
- Association of pharmaceutical wholesalers
- Professional Regulatory bodies (Pharmacy council etc...)

Legislative and legal framework/policies

There is a national medicines policy for the health sector. This does not speak specifics for antibiotics.
Standard guidelines exist for the use of antibiotics in the treatment of infectious disease. This serve as a guidance document only and there are no legal provisions to enforce adherence to the STG. The Ghana EML which is extracted from the STG serves only as basis for public procurement and also in defining the NHIA medicines list. (Seiter & Gyansa-Lutterodt, 2009)

Key issues

1. Inadequate strategic focus and support on the part of government in respect of the pharmaceutical sector. Increasing threat of loss of access to local markets is a stark reality. The local industry has an installed capacity for both liquid and solid forms to supply domestic needs as well as export. However this capacity is underutilized as a result of inadequate resources.
2. high production cost
3. high cost of borrowing making it difficult to compete with imports from SEA
4. lack of access to land earmarked specifically for pharmaceuticals production: due to the levels required by the WHO prequalification, pharma industries are to be sited from other industries for fear of contamination
5. lack of access to investment or developmental capital (Pharmaceutical Manufacturers Association of Ghana, 2014)
6. inadequate human resource
7. lack of bioequivalent centre
8. low tax incentives for the pharmaceutical industry
9. no market protection for finished product

Policy Statements

Preamble
Objective

Responsible Use of Antimicrobials

1. The Ministry of Health and its Agencies shall promote optimal prescribing and dispensing of antimicrobial agents at all levels of the health system.

2. The MOH and its Agencies, in collaboration with the training institutions shall incorporate rational use of antimicrobials into the curriculum in the training of healthcare professionals.

3. There shall be continuous education to promote the responsible use of antimicrobials in the general public.

4. The criteria for the selection of antimicrobials at the national level shall include surveillance data on antimicrobial resistance.

5. The MOH shall ensure that the prescribing and dispensing of antimicrobials are informed by laboratory results.

6. Increase coverage of national health insurance to improve access to healthcare (To consider deleting?)

7. The MOH, in collaboration with its agencies shall ensure that promotion and advertisement of antibiotics shall be restricted to health professionals and publications only.

8. Promotion and sales of antimicrobials shall not be permitted at unauthorized /public places such as lorry parks, funerals, markets and all modes of transportation, unless approved by appropriate authority.

9. There shall be the implementation of the standards for pharmaceutical management (selection, procurement, storage, distribution and use) at health facilities in line with the standards of pharmaceutical care

10. Drugs and Therapeutic Committees shall be encouraged to institute antimicrobial stewardship programmes in health facilities

Veterinary and Aquaculture

11. The Ministries of Food & Agriculture, Fisheries & Aquaculture Development, and related agencies shall promote responsible use of antimicrobials at all veterinary health settings.

12. There shall be instituted, monitoring mechanisms for the use of antimicrobials in all veterinary (including aquaculture) health settings.

13. The role of veterinary services in animal health and antibiotic use shall be promoted to assure public safety.

14. The standard treatment guidelines and SOPs for animal health shall be developed, disseminated and implemented.

15. There shall be standards set for antibiotic residue in veterinary and aquaculture.

16. There shall be continuous education to promote the responsible use of antimicrobials in animal husbandry.

17. The quality of laboratory services, including veterinary public health laboratories, shall be strengthened to inform selection and prescribing

Manufacturing, Supply, distribution, disposal

Disposal

18. There shall be established mechanisms for retrieving and disposal of unwholesome and unused antimicrobials from the general public and institutions

Supply

19. Sourcing, distribution and supply of antimicrobials shall strictly be in accordance with available regulatory instruments in the country. These shall include:

    -Health Profession Regulatory Bodies Act, Act 857
    -Public Health Act, Act 851
    -Health Institutions and Facilities Regulatory Act, Act

Manufacture

20. All local manufacturing companies shall have the basic infrastructural requirements as determined by the FDA for the manufacture of antimicrobial agents.

21. The Ministry of Health shall facilitate the establishment of a national bioequivalence centre to support the manufacture of quality generic antimicrobials

22. The FDA shall support local industries manufacturing antimicrobials to meet quality specifications.

23. There shall be strengthened collaboration between academia and industry for the development of new antimicrobial agents.

24. The government shall provide incentives and financial support for local industries to produce affordable but quality antimicrobials including industries with the capacity to develop APIs for the pharmaceutical sector

25. Innovation for new antimicrobial agents shall be encouraged including those from herbal sources

Regulation and enforcement

26. Supply of antimicrobial agents shall be strictly according to laid down regulations (Public Health Act, Health Professions Regulatory Bodies Act, HFRA (Consider carefully)

27. The FDA and other relevant institutions shall enhance post market surveillance and pharmacovigilance on antimicrobial agents

National surveillance

28. There shall be established national monitoring systems for antimicrobial use and surveillance of antimicrobial resistance.

29. Disease control programmes shall be strengthened to monitor resistance to antimicrobials (Consider carefully)

30. There shall be data visibility and reporting of all surveillance data to inform policy (Consider carefully)

Infection prevention and control

31. The Ministry of Health Infection prevention and control policies and guidelines shall be implemented in all health facilities.

    In addition, special emphasis shall be placed on the following areas:
    - Hand hygiene

- Sterilization and disinfection
- Use of personal protective equipment
- Environmental cleaning and waste management
- Isolation

32. The Waste management policy of the Ministry of Health shall be implemented in all health care settings

Laboratory services

33. Government shall resource to improve on the quality of laboratory diagnostic services to inform the selection and prescribing of antimicrobials

34. The National laboratory policy shall be implemented in all healthcare facilities. District hospital laboratories shall be strengthened to provide culture and sensitivity services.

Research and development

35. The Ministry of Health shall collaborate with other agencies and institutions to conduct research into various aspects of Antimicrobial use and resistance in humans and animals

36. Basic and operational research in antibiotic use and resistance and development of new antimicrobial agents, vaccines and diagnostics shall be encouraged

Stakeholder collaboration and Governance of Antimicrobial resistance

37. The Ministry of Health shall promote collaboration, provide leadership and stewardship, amongst stakeholders, at international and national levels, as well as other sectors on antimicrobial use and resistance

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